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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,808	12/07/2001	H. William Bosch	029318-0799	8203

7590 05/20/2005

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EXAMINER

TRAN, SUSAN T

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

10/004,808

Applicant(s)

BOSCH ET AL.

Examiner

Susan T. Tran

Art Unit

1615

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 18 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: 39-50.  
Claim(s) objected to: 16, 25, 33, 38, 63, 76, 94, 96, 97, 105 and 106.  
Claim(s) rejected: 14, 15, 17-24, 26-32, 34-37, 51-62, 64-75, 93, 95, 98-104, 107-110.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Clarification of the status of the claims:

Claims 14-76 and 93-110 are pending.

Claims 16, 25, 33, 38, 63, 76, 94, 96, 97, 105 and 106 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 39-50 are allowed.

Applicant's arguments filed 04/18/05 have been fully considered but they are not persuasive.

Applicant argues that Pace fails to teach crystalline particles and instead teaches amorphous particles. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., crystalline particles) is not recited in independent claims 27, 51, 64 and 93. Furthermore, claim 93 recites "amorphous" state. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding rejected claims 14 and 95 over Pace, applicant argues that the Examiner has not established any motivation to substitute crystalline particles for the amorphous particles of Pace, and therefore, the examiner's "lack of criticality" argument fails to address the deficiencies of Pace. However, although Pace is silent as to the teaching of the crystalline particles, Pace teaches the objective of the present invention is to

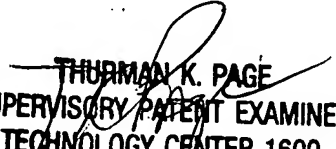
develop a process with high productivity based on the use of liquefied gas solvents, including supercritical fluid technology, that yields surface modifier stabilized suspensions of water insoluble drugs with an average particle size of 50 nm to about 2000 nm and narrow size distribution. It is noted that the compositions having particle size within the claimed size ranges. The drug particles of the composition taught by Pace is not aggregate and thereby improve both their storage stability and pharmacokinetic properties. Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable size and shape of the particle to obtain the claimed invention. It is noted that Pave recognizes the properties desired by applicant. Furthermore, it is noted that even applicant permits amorphous, semi-crystalline, or any combination of amorphous, and semi-crystalline (see claim 93, and page 26, 3<sup>rd</sup> paragraph). Accordingly, there's no criticality in the crystalline particle being claimed. Applicant's attention is called to column 3, lines 20-25, Pace teaches the particles are stable and do not appreciably flocculate or agglomerate, and can be formulated into pharmaceutical compositions exhibiting unexpectedly high bioavailability.

Applicant argues that Pace fails to teach compositions comprising *liquid* particles but rather teaches only solid particles. However, nowhere in the claims the Examiner finds the limitation "liquid particles" being recited. The claim requires the active agent particles be dispersed in a liquid medium in which they are poorly soluble. Pace teaches the drug particles are dispersed in the aqueous medium and the liquefied gas

contains only the water insoluble substance (column 4, lines 48-62). Accordingly, Pace does teach or suggest the invention of claims 27-38, 103 and 104.

Applicant argues that Pace fails to teach or suggest droplets comprising active agent. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., droplets comprising active agent) is not recited in the rejected claims. claim 51 requires active agent dissolved or dispersed in liquid droplets. Thus, according to the language of claim 51, active agent can dissolved in liquid. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that there is no motivation to combine Pace and Liversidge or Cutie. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Liversidge is cited solely for the teaching of the specific carrier; and Cutie is combined with Pace solely for the teaching of the specific active agent.

  
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